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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Court et al.
Application No. 10/692,553
Filed: October 23, 2003
Confirmation No. 1179
For: ENHANCED HOMOLOGOUS RECOMBINATION MEDIATED BY LAMBDA RECOMBINATION PROTEINS
Examiner: Jennifer Ann Dunston
Art Unit: 1636
Attorney Reference No. 4239-66898-01

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: MAIL STOP PETITION, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Attorney or Agent for Applicant(s) _____

Date Mailed October 16, 2006

MAIL STOP PETITION
COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

TRANSMITTAL LETTER

Enclosed for filing in the application referenced above are the following:

- ☒ Petition for Acceptance of a Declaration Signed by Other Than All The Inventors (w/attached copy of Combined Declaration and Power of Attorney, Assignment, and Declaration Under § 37 C.F.R. 1.131)
- ☒ Statement by Susan Alpert Siegel, Ph.D. (w/attached copy of Express Mail Label, Email, Internet Search)
- ☒ A check in the amount of $130.00 covering petition fee is enclosed.
- ☒ The Director is hereby authorized to charge any additional fees that may be required, or credit over-payment, to Deposit Account No. 02-4550. A copy of this sheet is enclosed.
- ☒ Please return the enclosed postcard to confirm that the items listed above have been received.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By _____
Susan Alpert Siegel, Ph.D.
Registration No. 43,121

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Attorney or Agent for Applicant(s)

Date Mailed: October 16, 2006

MAIL STOP PETITION
COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

PETITION FOR ACCEPTANCE OF A DECLARATION SIGNED BY OTHER THAN ALL THE INVENTORS

Dear Sir:

Applicants Neal Copeland, Daiguan Yu, Donald E. Court, E-Chiang Lee, Nancy A. Jenkins, and Pentao Liu hereby petition the Commissioner to accept the filing of the Declaration Under 37 C.F.R. § 1.131 signed by other than all the inventors.

1. Hilary M. Ellis is an inventor of the above-referenced application, and was under an obligation to assign her rights to The Government of the United States of America as represented by the Secretary, Department of Health and Human Services, National Institutes of Health at the time the application was filed. Hilary M. Ellis executed the Declaration and Combined Power of Attorney for the above-referenced application on May 11, 2003 and executed an Assignment for the above-referenced application on May 12, 2003. A copy of the Combined Declaration and Power of Attorney and the Assignment are enclosed (Exhibits 1 and 2). At that time Hilary M. Ellis resided in San Ramon, CA.

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2. A Declaration Under 37 C.F.R. § 1.131 (hereinafter "the Declaration") was filed on August 22, 2006. This Declaration was executed by all the inventors other than Hilary M. Ellis. A copy of the Declaration is enclosed (Exhibit 3).

3. The last known mailing address for Hilary M. Ellis is as follows:

7598 Interlachen Avenue
San Ramon, CA 94583

However, Hilary M. Ellis is no longer at her last known mailing address, and could not be reached to sign the Declaration. A Statement by the undersigned providing the pertinent facts establishing that co-inventor Hilary M. Ellis cannot be reached is enclosed.

4. The M.P.E.P § 715.04 (C) states:

> "Affidavits or declarations to overcome a rejection of a claim or claims must be made by the inventor or inventors of the subject matter of the rejected claim(s), a party qualified under 37 CFR 1.42, 1.43, or 1.47, or the assignee or other party in interest when it is not possible to produce the affidavit or declaration of the inventor(s)..... *Further, where it is shown that a joint inventor is deceased, refuses to sign, or is otherwise unavailable, the signatures of the remaining joint inventors are sufficient.*" [emphasis added]

4. In view of the unavailability of Hilary M. Ellis to sign the Declaration, Applicants believe that they are entitled to make such filing on behalf of Hilary M. Ellis pursuant to 37 C.F.R. § 1.47. Applicants request that the Declaration, without the signature of Hilary M. Ellis, be accepted by the U.S. Patent and Trademark Office. The fee required by § 1.17(g) also is enclosed.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

By _____
Susan Alpert Siegel, Ph.D.
Registration No. 43,121

COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled ENHANCED HOMOLOGOUS RECOMBINATION MEDIATED BY LAMBDA RECOMBINATION PROTEINS, the specification of which

☐ is attached hereto.

☒ was filed on February 12, 2003 as United States Application No. 10/366,044.

☐ was described and claimed in PCT International Application No. _____, filed on _____, and as amended under PCT Article 19 on _____ (if applicable).

☐ and was amended on _____ (if applicable).

☐ with amendments through _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

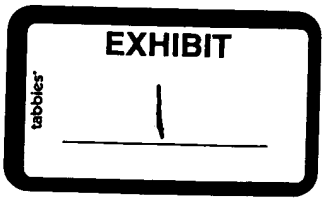
I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56. If this is a continuation-in-part application filed under the conditions specified in 35 U.S.C. § 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, I further acknowledge the duty to disclose material information as defined in 37 CFR § 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of an PCT International application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT International application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) on which priority is claimed:

Prior Foreign Application(s)	Country	Filing Date	Priority Claimed
			☐ Yes ☐ No

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date
60/225,164	August 14, 2000
60/271,632	February 26, 2001



I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or § 365(c) of any PCT International application(s) designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States

Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT International filing date of this application:

Application No.	Filing Date	Status: patented, pending, abandoned
PCT/US01/25507	August 14, 2001	Pending at time of filing

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application, to file a corresponding international application, and to transact all business in the Patent and Trademark Office connected therewith:

Name	Reg. No.	Name	Reg. No.
Dale Berkley	42,319	Norbert Pontzer	40,777
Steven Ferguson	38,488	Richard U. Rodriguez	45,980
Stephen Finley	36,357	Susan S. Rucker	35,762
James C. Haight	25,588	David R. Sadowski	32,808
Catherine M. Joyce	40,668	Marlene Shinn	46,005
John Peter Kim	38,514	Jack Spiegel	34,477

with an Associate Power of Attorney to the following:

Name	Reg. No.	Name	Reg. No.
BENDERLY, Kenneth M.	51,453	NOONAN, William D.	30,878
BIBLE, Patrick M.	44,423	ORR, David E.	44,988
BUNKER, Gillian	47,461	PETERSEN, David P.	28,106
CALDWELL, Lisa M.	41,653	POLLEY, Richard J.	28,107
CARLSON, Anne	47,472	RINEHART, Kyle B.	47,027
GIRARD, Michael P.	38,467	RUPERT, Wayne W.	34,420
GOFF, Jared S.	44,716	RYBAK, Sheree L.	47,913
HAENDLER, Jeffrey B.	43,652	SIEGEL, Susan Alpert	43,121
HARDING, Tanya M.	42,630	SLATER, Stacey C.	36,011
JAKUBEK, Joseph T.	34,190	STEPHENS Jr., Donald L.	34,022
JONCUS, Stephen J.	44,809	STUART, John W.	24,540
JONES, Michael D.	41,879	VANDENBERG, John D.	31,312
KLARQUIST, Kenneth S.	16,445	WHINSTON, Arthur L.	19,155
KLITZKE II, Ramon A.	30,188	WIGHT, Stephen A.	37,759
LEIGH, James S.	20,434	WINN, Garth A.	33,220
MC LEOD, Richard D.	46,921	YOUNG, Travis	53,819
MAURER, Gregory L.	43,781	ZASTROW, Devon J.	50,206

all of the law firm of Klarquist Sparkman, LLP.

Address all telephone calls to Susan Alpert Siegel, Ph.D., telephone number 503/226-7391 and facsimile number 503/228-9446.

Address all correspondence to:

KLARQUIST SPARKMAN, LLP
One World Trade Center, Suite 1600
121 SW Salmon Street
Portland, OR 97204-2988

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made

with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of First Joint Inventor: Donald L. Court

Inventor's Signature _____ Date _____

Residence: Frederick, Maryland

Citizenship: United States of America

Post Office Address: 502 Magnolia Avenue, Frederick, Maryland, 21702

Full Name of Second Joint Inventor: Daiguan Yu

Inventor's Signature _____ Date _____

Residence: Frederick, Maryland

Citizenship: United States of America

Post Office Address: 1418 Taney Avenue, H301, Frederick, Maryland, 21702

Full Name of Third Joint Inventor: E-Chiang Lee

Inventor's Signature _____ Date _____

Residence: Frederick, Maryland

Citizenship: Taiwan

Post Office Address: 2402 Dominion Drive, No. 2C, Frederick, Maryland, 21702

Full Name of Fourth Joint Inventor: Hilary M. Ellis

Inventor's Signature Hilary M Ellis 5/11/03
Date

Residence: ~~Bethesda, Maryland~~ San Ramon, California Home 5/11/03

Citizenship: United States of America

Post Office Address: ~~4713 Edgefield Road, Bethesda, Maryland, 20814~~
7598 Interlachen Ave. San Ramon, CA 94583

Full Name of Fifth Joint Inventor: Nancy A. Jenkins

Inventor's Signature _____ _____
Date

Residence: Ijamsville, Maryland

Citizenship: United States of America

Post Office Address: 10022 Pebble Beach Terrace, Ijamsville, Maryland, 21754

Full Name of Sixth Joint Inventor: Pentao Liu

Inventor's Signature _____ _____
Date

Residence: Frederick, Maryland

Citizenship: China

Post Office Address: 1402 Baker Place West, No. 21, Frederick, Maryland, 21702

Full Name of Seventh Joint Inventor: Neal G. Copeland

Inventor's Signature _____ _____
Date

Residence: Ijamsville, Maryland

Citizenship: United States of America

Post Office Address: 10022 Pebble Beach Terrace, Ijamsville, Maryland, 21754

WDN/SAS:gte 10/23/03 E-177-2000/2-US-02 222564

10-23-03

Atty. Ref. No. 4239-66898
Express Mail Label No. EV339201050US

RECORDATION F 11-04-2003 **TS ONLY**

MAIL STOP PATENT APPLICATION
DIRECTOR FOR PATENTS
PO BOX 1450
ALEXANDRIA, VA 22313-1450

102591527

0727 U.S.PTO 10/692553 102303

1. Total number of pages including cover sheet, attachments and document: 17

2. Name of Conveying Party(ies) and Execution Date(s) of Document(s) ☐ **Check here if additional name(s) attached**

Name(s): Donald L. Court[1], Daiguan Yu[2], E-Chiang Lee[3], Hilary M. Ellis[4], Nancy A. Jenkins[5], Pentao Liu[6], and Neal G. Copeland[7]

Execution Date(s): March 31, 2003[1,5,6,7]; May 5, 2003[2]; May 6, 2003[3]; and May 12, 2003[4]

3. Name and address of receiving party ☐ **Check here if additional name(s) & address(es) are attached**

Name: THE GOVERNMENT OF THE UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Address: National Institutes of Health
Office of Technology Transfer, Suite 325
6011 Executive Boulevard

City: Rockville State/Country: MD 10692553 Zip: 20852

4. Nature of Conveyance

☒ Assignment ☐ Merger ☐ Security Agreement ☐ Name Change ☐ Other:

5. Total number of applications and patents involved: One

6. Total Fee Enclosed (37 C.F.R. § 3.41): $40.00

7. ☒ **Check here if any deficiency/overpayment is authorized to be charged to deposit account 02-4550**

8. Enter either the Execution date (of the Declaration and Power of Attorney), Application Number, or the Patent Number. Do not enter more than one number for the same patent.

A. ☒ This document is being filed with a new application.
B. ☐ Patent Application No.(s) or Patent No.(s):
☐ **Check here if additional numbers are attached**

9. Correspondent's name, address, and telephone number

Susan Alpert Siegel, Ph.D.
Klarquist Sparkman, LLP
One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204-2988
Telephone: 503-226-7391

10. ☒ **Please return the attached postcard to confirm that these items have been received.**

11. Statement and signature *To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.*

Susan Alpert Siegel, Ph.D.		October 23, 2003
Name of Person Signing	Signature	Date

EXHIBIT 2

cc: Client
Docketing

ASSIGNMENT

We, Donald L. Court, of Frederick, Maryland, a citizen the United States of America, Daiguan Yu, of Frederick, Maryland, a citizen of the United States of America, E-Chiang Lee, of Frederick, Maryland, a citizen of Taiwan, Hilary M. Ellis, of Bethesda, Maryland, a citizen of the United States of America, Nancy A. Jenkins, of Ijamsville, Maryland, a citizen of the United States of America, Pentao Liu, of Frederick, Maryland, a citizen of China, and Neal G. Copeland, of Ijamsville, Maryland, a citizen of the United States of America, employees of the Department of Health and Human Services at the time the invention was made, have invented ENHANCED HOMOLOGOUS RECOMBINATION MEDIATED BY LAMBDA RECOMBINATION PROTEINS for which the following patent applications have been filed:

U.S. Patent Application No. 60/225,164, filed August 14, 2000;
U.S. Patent Application No. 60/271,632, filed February 26, 2001;
PCT Patent Application No. PCT/US01/25507, filed August 14, 2001; and
U.S. Patent Application No. 10/366,044, filed February 12, 2002.

We were employed by the Department of Health and Human Services at the time the invention was made. The conditions under which said invention was made are such as to entitle the Government of the United States of America under Paragraph 1(a) of Executive order 10096, to the entire right, title, and interest in the invention, in the United States and all other countries throughout the world.

In consideration of our obligations under Executive Order 10096, and other valuable consideration, we the undersigned, have sold, assigned, and transferred and do sell, assign, and transfer to The Government of the United States of America as represented by the Secretary of the Department of Health and Human Services (hereinafter THE GOVERNMENT), and their successors and assigns, the full and exclusive right, title, and interest in the patent applications and invention throughout the United States of America, its territories and dependencies, and all other countries. This includes an assignment of all Letters Patents that may be granted on the invention in the United States of America and all countries throughout the world, and any divisional, renewal, continuation in whole or in part, substitution, conversion, reissue, prolongation or extension thereof; and the right to claim priority from the patent applications as provided for by United States law, the Patent Cooperation Treaty, the European Patent Convention, the Paris Convention, or other applicable law.

We authorize and request the issuance of said Letters Patent to THE GOVERNMENT, as an assignee of the entire right, title, and interest to be held as fully and entirely as the same would have been held by us had this assignment not been made.

We warrant that there are no outstanding assignments, grants, liens, encumbrances, or agreements either written, oral, or implied that will impair, diminish, limit, or abridge the interest herein conveyed at the time of the execution of the present assignment.

We also agree upon reasonable request to communicate to THE GOVERNMENT, its representatives, assigns or agents, any facts known to us respecting the invention, and to testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths, provide all requested documents, and do everything reasonably possible to aid THE GOVERNMENT and its assigns to obtain and enforce proper patent protection for the invention in the United States or any foreign country. These provisions are binding upon our heirs, legal representatives, administrators and assigns.

We have authorized THE GOVERNMENT to file and prosecute these patent applications, as well as any corresponding international or national applications that claim priority from them. THE GOVERNMENT has the right to select attorneys or agents of its choice to prosecute at its discretion these applications on its behalf.

We grant the law firm of Klarquist Sparkman, LLP, the power to insert on this Assignment any further information that may be necessary or desirable in order to comply with all applicable legal requirements, including the rules of the United States Patent and Trademark Office, for submitting and recording this document.

IN TESTIMONY WHEREOF, Assignors have signed their names on the dates indicated.

Dated: 3/31/03

Donald L. Court

STATE OF Maryland)
) ss.
COUNTY OF Frederick)

This 31 day of March, 2003, before me personally came the above-named Donald L. Court, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

Ann E. Rogers
Notary Public for Maryland
My commission expires: 04/01/05

[SEAL]

Dated: _____

_____
Daiguan Yu

STATE OF _____)
) ss.
COUNTY OF _____)

This ___ day of _____, _____, before me personally came the above-named Daiguan Yu, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
E-Chiang Lee

STATE OF _____)
) ss.
COUNTY OF _____)

This ___ day of _____ , _____ , before me personally came the above-named E-Chiang Lee, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
Hilary M. Ellis

STATE OF _____)
) ss.
COUNTY OF _____)

This ___ day of _____ , _____ , before me personally came the above-named Hilary M. Ellis, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: 3/31/03

Nancy A. Jenkins
Nancy A. Jenkins

STATE OF Maryland)
) ss.
COUNTY OF Frederick)

This 31 day of March , 2003 , before me personally came the above-named Nancy A. Jenkins, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

Ann E. Rogers
Notary Public for Maryland
My commission expires: 07/01/05

[SEAL]

Dated: 3/31/03

Pentao Liu

STATE OF Maryland)
) ss.
COUNTY OF Frederick)

This 31 day of March, 2003, before me personally came the above-named Pentao Liu, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

Ann E. Rogers
Notary Public for Maryland
My commission expires: 04/01/05

[SEAL]

Dated: 3/31/03

Neal G. Copeland

STATE OF Maryland)
) ss.
COUNTY OF Frederick)

This 31 day of March, 2003, before me personally came the above-named Neal G. Copeland, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

Ann E. Rogers
Notary Public for Maryland
My commission expires: 04/01/05

[SEAL]

ASSIGNMENT

of The Woodlands, Texas, a citizen of China (D.Y.)

We, Donald L. Court, of Frederick, Maryland, a citizen the United States of America, Daiguan Yu, ~~of Frederick, Maryland, a citizen of the United States of America,~~ E-Chiang Lee, of Frederick, Maryland, a citizen of Taiwan, Hilary M. Ellis, of Bethesda, Maryland, a citizen of the United States of America, Nancy A. Jenkins, of Ijamsville, Maryland, a citizen of the United States of America, Pentao Liu, of Frederick, Maryland, a citizen of China, and Neal G. Copeland, of Ijamsville, Maryland, a citizen of the United States of America, employees of the Department of Health and Human Services at the time the invention was made, have invented ENHANCED HOMOLOGOUS RECOMBINATION MEDIATED BY LAMBDA RECOMBINATION PROTEINS for which the following patent applications have been filed:

U.S. Patent Application No. 60/225,164, filed August 14, 2000;
U.S. Patent Application No. 60/271,632, filed February 26, 2001;
PCT Patent Application No. PCT/US01/25507, filed August 14, 2001; and
U.S. Patent Application No. 10/366,044, filed February 12, 2002.

We were employed by the Department of Health and Human Services at the time the invention was made. The conditions under which said invention was made are such as to entitle the Government of the United States of America under Paragraph 1(a) of Executive order 10096, to the entire right, title, and interest in the invention, in the United States and all other countries throughout the world.

In consideration of our obligations under Executive Order 10096, and other valuable consideration, we the undersigned, have sold, assigned, and transferred and do sell, assign, and transfer to The Government of the United States of America as represented by the Secretary of the Department of Health and Human Services (hereinafter THE GOVERNMENT), and their successors and assigns, the full and exclusive right, title, and interest in the patent applications and invention throughout the United States of America, its territories and dependencies, and all other countries. This includes an assignment of all Letters Patents that may be granted on the invention in the United States of America and all countries throughout the world, and any divisional, renewal, continuation in whole or in part, substitution, conversion, reissue, prolongation or extension thereof; and the right to claim priority from the patent applications as provided for by United States law, the Patent Cooperation Treaty, the European Patent Convention, the Paris Convention, or other applicable law.

We authorize and request the issuance of said Letters Patent to THE GOVERNMENT, as an assignee of the entire right, title, and interest to be held as fully and entirely as the same would have been held by us had this assignment not been made.

We warrant that there are no outstanding assignments, grants, liens, encumbrances, or agreements either written, oral, or implied that will impair, diminish, limit, or abridge the interest herein conveyed at the time of the execution of the present assignment.

We also agree upon reasonable request to communicate to THE GOVERNMENT, its representatives, assigns or agents, any facts known to us respecting the invention, and to testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths, provide all requested documents, and do everything reasonably possible to aid THE GOVERNMENT and its assigns to obtain and enforce proper patent protection for the invention in the United States or any foreign country. These provisions are binding upon our heirs, legal representatives, administrators and assigns.

We have authorized THE GOVERNMENT to file and prosecute these patent applications, as well as any corresponding international or national applications that claim priority from them. THE GOVERNMENT has the right to select attorneys or agents of its choice to prosecute at its discretion these applications on its behalf.

We grant the law firm of Klarquist Sparkman, LLP, the power to insert on this Assignment any further information that may be necessary or desirable in order to comply with all applicable legal requirements, including the rules of the United States Patent and Trademark Office, for submitting and recording this document.

IN TESTIMONY WHEREOF, Assignors have signed their names on the dates indicated.

Dated:_____

_____
Donald L. Court

STATE OF _____)
) ss.
COUNTY OF _____)

This ___ day of _____, ____, before me personally came the above-named Donald L. Court, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: 5-5-03

Daiguan Yu

STATE OF Texas)
) ss.
COUNTY OF Montgomery)

This 5th day of May, 2003, before me personally came the above-named Daiguan Yu, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

Michelle Klein
Notary Public for State of Texas
My commission expires:

[SEAL]

MICHELLE KLEIN
Notary Public, State of Texas
My Commission Expires
February 13, 2005

Dated: _____

_____
E-Chiang Lee

STATE OF _____)
) ss.
COUNTY OF _____)

This ___ day of _____, _____, before me personally came the above-named E-Chiang Lee, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
Hilary M. Ellis

STATE OF_____)
) ss.
COUNTY OF _____)

This ___ day of _____, _____, before me personally came the above-named Hilary M. Ellis, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
Nancy A. Jenkins

STATE OF_____)
) ss.
COUNTY OF _____)

This ___ day of _____, _____, before me personally came the above-named Nancy A. Jenkins, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
Pentao Liu

STATE OF_____)
) ss.
COUNTY OF _____)

This ___ day of _____, _____, before me personally came the above-named Pentao Liu, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
Neal G. Copeland

STATE OF_____)
) ss.
COUNTY OF _____)

This ___ day of _____, _____, before me personally came the above-named Neal G. Copeland, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

ASSIGNMENT

We, Donald L. Court, of Frederick, Maryland, a citizen the United States of America, Daiguan Yu, of Frederick, Maryland, a citizen of the United States of America, E-Chiang Lee, of ~~Frederick~~, The Woodland Texas ~~Maryland,~~ a citizen of Taiwan, Hilary M. Ellis, of Bethesda, Maryland, a citizen of the United States of America, Nancy A. Jenkins, of Ijamsville, Maryland, a citizen of the United States of America, Pentao Liu, of Frederick, Maryland, a citizen of China, and Neal G. Copeland, of Ijamsville, Maryland, a citizen of the United States of America, employees of the Department of Health and Human Services at the time the invention was made, have invented ENHANCED HOMOLOGOUS RECOMBINATION MEDIATED BY LAMBDA RECOMBINATION PROTEINS for which the following patent applications have been filed:

EL 7/5/03

U.S. Patent Application No. 60/225,164, filed August 14, 2000;
U.S. Patent Application No. 60/271,632, filed February 26, 2001;
PCT Patent Application No. PCT/US01/25507, filed August 14, 2001; and
U.S. Patent Application No. 10/366,044, filed February 12, 2002.

We were employed by the Department of Health and Human Services at the time the invention was made. The conditions under which said invention was made are such as to entitle the Government of the United States of America under Paragraph 1(a) of Executive order 10096, to the entire right, title, and interest in the invention, in the United States and all other countries throughout the world.

In consideration of our obligations under Executive Order 10096, and other valuable consideration, we the undersigned, have sold, assigned, and transferred and do sell, assign, and transfer to The Government of the United States of America as represented by the Secretary of the Department of Health and Human Services (hereinafter THE GOVERNMENT), and their successors and assigns, the full and exclusive right, title, and interest in the patent applications and invention throughout the United States of America, its territories and dependencies, and all other countries. This includes an assignment of all Letters Patents that may be granted on the invention in the United States of America and all countries throughout the world, and any divisional, renewal, continuation in whole or in part, substitution, conversion, reissue, prolongation or extension thereof; and the right to claim priority from the patent applications as provided for by United States law, the Patent Cooperation Treaty, the European Patent Convention, the Paris Convention, or other applicable law.

We authorize and request the issuance of said Letters Patent to THE GOVERNMENT, as an assignee of the entire right, title, and interest to be held as fully and entirely as the same would have been held by us had this assignment not been made.

We warrant that there are no outstanding assignments, grants, liens, encumbrances, or agreements either written, oral, or implied that will impair, diminish, limit, or abridge the interest herein conveyed at the time of the execution of the present assignment.

We also agree upon reasonable request to communicate to THE GOVERNMENT, its representatives, assigns or agents, any facts known to us respecting the invention, and to testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths, provide all requested documents, and do everything reasonably possible to aid THE GOVERNMENT and its assigns to obtain and enforce proper patent protection for the invention in the United States or any foreign country. These provisions are binding upon our heirs, legal representatives, administrators and assigns.

PC

We have authorized THE GOVERNMENT to file and prosecute these patent applications, as well as any corresponding international or national applications that claim priority from them. THE GOVERNMENT has the right to select attorneys or agents of its choice to prosecute at its discretion these applications on its behalf.

We grant the law firm of Klarquist Sparkman, LLP, the power to insert on this Assignment any further information that may be necessary or desirable in order to comply with all applicable legal requirements, including the rules of the United States Patent and Trademark Office, for submitting and recording this document.

IN TESTIMONY WHEREOF, Assignors have signed their names on the dates indicated.

Dated:_____ _____
Donald L. Court

STATE OF _____)
) ss.
COUNTY OF _____)

This ___ day of _____ , _____ , before me personally came the above-named Donald L. Court, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____ _____
Daiguan Yu

STATE OF _____)
) ss.
COUNTY OF _____)

This ___ day of _____ , _____ , before me personally came the above-named Daiguan Yu, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: 5-6-03

E-Chiang Lee

STATE OF Texas)
) ss.
COUNTY OF Montgomery)

This 6th day of May, 2003, before me personally came the above-named E-Chiang Lee, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

Notary Public for E-Chiang Lee
My commission expires:

ALLYSON MANN
Notary Public, State of Texas
My Commission Expires
March 09, 2004

[SEAL]

Dated: _____

Hilary M. Ellis

STATE OF_____)
) ss.
COUNTY OF _____)

This ___ day of _____, ____, before me personally came the above-named Hilary M. Ellis, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

Nancy A. Jenkins

STATE OF_____)
) ss.
COUNTY OF _____)

This ___ day of _____, ____, before me personally came the above-named Nancy A. Jenkins, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
Pentao Liu

STATE OF_____)
) ss.
COUNTY OF _____)

This ___ day of _____ , _____ , before me personally came the above-named Pentao Liu, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
Neal G. Copeland

STATE OF_____)
) ss.
COUNTY OF _____)

This ___ day of _____ , _____ , before me personally came the above-named Neal G. Copeland, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

ASSIGNMENT

We, Donald L. Court, of Frederick, Maryland, a citizen the United States of America, Daiguan Yu, of Frederick, Maryland, a citizen of the United States of America, E-Chiang Lee, of Frederick, Maryland, a citizen of Taiwan, Hilary M. Ellis, of ~~Bethesda, Maryland~~ San Ramon, California, a citizen of the United States of America, Nancy A. Jenkins, of Ijamsville, Maryland, a citizen of the United States of America, Pentao Liu, of Frederick, Maryland, a citizen of China, and Neal G. Copeland, of Ijamsville, Maryland, a citizen of the United States of America, employees of the Department of Health and Human Services at the time the invention was made, have invented ENHANCED HOMOLOGOUS RECOMBINATION MEDIATED BY LAMBDA RECOMBINATION PROTEINS for which the following patent applications have been filed:

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U.S. Patent Application No. 60/271,632, filed February 26, 2001;
PCT Patent Application No. PCT/US01/25507, filed August 14, 2001; and
U.S. Patent Application No. 10/366,044, filed February 12, 2002.

We were employed by the Department of Health and Human Services at the time the invention was made. The conditions under which said invention was made are such as to entitle the Government of the United States of America under Paragraph 1(a) of Executive order 10096, to the entire right, title, and interest in the invention, in the United States and all other countries throughout the world.

In consideration of our obligations under Executive Order 10096, and other valuable consideration, we the undersigned, have sold, assigned, and transferred and do sell, assign, and transfer to The Government of the United States of America as represented by the Secretary of the Department of Health and Human Services (hereinafter THE GOVERNMENT), and their successors and assigns, the full and exclusive right, title, and interest in the patent applications and invention throughout the United States of America, its territories and dependencies, and all other countries. This includes an assignment of all Letters Patents that may be granted on the invention in the United States of America and all countries throughout the world, and any divisional, renewal, continuation in whole or in part, substitution, conversion, reissue, prolongation or extension thereof; and the right to claim priority from the patent applications as provided for by United States law, the Patent Cooperation Treaty, the European Patent Convention, the Paris Convention, or other applicable law.

We authorize and request the issuance of said Letters Patent to THE GOVERNMENT, as an assignee of the entire right, title, and interest to be held as fully and entirely as the same would have been held by us had this assignment not been made.

We warrant that there are no outstanding assignments, grants, liens, encumbrances, or agreements either written, oral, or implied that will impair, diminish, limit, or abridge the interest herein conveyed at the time of the execution of the present assignment.

We also agree upon reasonable request to communicate to THE GOVERNMENT, its representatives, assigns or agents, any facts known to us respecting the invention, and to testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths, provide all requested documents, and do everything reasonably possible to aid THE GOVERNMENT and its assigns to obtain and enforce proper patent protection for the invention in the United States or any foreign country. These provisions are binding upon our heirs, legal representatives, administrators and assigns.

We have authorized THE GOVERNMENT to file and prosecute these patent applications, as well as any corresponding international or national applications that claim priority from them. THE GOVERNMENT has the right to select attorneys or agents of its choice to prosecute at its discretion these applications on its behalf.

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IN TESTIMONY WHEREOF, Assignors have signed their names on the dates indicated.

Dated:_____

_____
Donald L. Court

STATE OF _____)
) ss.
COUNTY OF _____)

This ___ day of _____, _____, before me personally came the above-named Donald L. Court, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
Daiguan Yu

STATE OF _____)
) ss.
COUNTY OF _____)

This ___ day of _____, _____, before me personally came the above-named Daiguan Yu, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
E-Chiang Lee

STATE OF _____)
) ss.
COUNTY OF _____)

This ___ day of _____, ____, before me personally came the above-named E-Chiang Lee, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: May 12, 2003

Hilary M. Ellis

STATE OF California)
) ss.
COUNTY OF Contra) Costa

This 12 day of May, 2003, before me personally came the above-named Hilary M. Ellis, who executed the foregoing Assignment in my presence, and who acknowledged to me that ~~he~~ she executed the same of ~~his~~ her own free will for the purposes set forth therein.

JUSTIN TESSLER
Commission # 1219865
Notary Public - California
Contra Costa County
My Comm. Expires May 16, 2003

_____
Notary Public for CA
My commission expires:

[SEAL]

Dated: _____

_____
Nancy A. Jenkins

STATE OF _____)
) ss.
COUNTY OF _____)

This ___ day of _____, ____, before me personally came the above-named Nancy A. Jenkins, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
Pentao Liu

STATE OF_____)
) ss.
COUNTY OF _____)

This ___ day of _____, _____, before me personally came the above-named Pentao Liu, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

Dated: _____

_____
Neal G. Copeland

STATE OF_____)
) ss.
COUNTY OF _____)

This ___ day of _____, _____, before me personally came the above-named Neal G. Copeland, who executed the foregoing Assignment in my presence, and who acknowledged to me that he executed the same of his own free will for the purposes set forth therein.

_____
Notary Public for _____
My commission expires:

[SEAL]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Court et al.
Application No. 10/692,553
Filed: October 23, 2003
Confirmation No. 1179
For: ENHANCED HOMOLOGOUS RECOMBINATION MEDIATED BY LAMBDA RECOMBINATION PROTEINS
Examiner: Jennifer Ann Dunston
Art Unit: 1636
Attorney Reference No. 4239-66898-01

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Attorney or Agent for Applicant(s)

Date Mailed August 24, 2006

MAIL STOP AMENDMENT
COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

We, Neal Copeland, Daiguan Yu, Hilary M. Ellis, Donald E. Court, E-Chiang Lee, Nancy A. Jenkins, and Pentao Liu, declare as follows:

1. We are the inventors of the above-identified application, which is a continuation of U.S. Patent Application No. 10/366,044, filed February 12, 2003, which is a continuation-in-part of PCT Application No. PCT US01/25507, filed August 14, 2001, which claims the benefit of U.S. Provisional Application No. 60/225, 164, filed August 14, 2000 and claims the benefit of U.S. Provisional Application No. 60/271,632, filed February 21, 2001.

2. It is our understanding that the claims 1, 3, 4 and 13 are rejected as allegedly being anticipated by Cassanova et al., Genesis 32(2): 158-160, published online February 13, 2002.

3. We conceived of, and reduced to practice, a method for generating a vector for conditional knockout of a gene in a cell including a de-repressible promoter operably linked to a

EXHIBIT
tabbies
3

nucleic acid encoding Beta and Exo, as claimed in claims 1, and 2-13, prior to February 13, 2002, in the United States.

3. The methods of claims 1, 3, 4 and 13 were conceived of prior to February 13, 2003. Selection cassettes for use in the claimed methods were made and improved prior to February 13, 2002; some of the experimental work conducted prior to February 13, 2002 is described below. Photocopies of Dr. Liu's laboratory notebook pages, labeled pages 1-10 are submitted herewith. The photocopied pages are referred to below as "the laboratory notes." Dates on these pages have been redacted. Prior to February 13, 2002, we performed the following experiments in the United States, which are documented on the laboratory notebook pages:

We constructed a plasmid that including a selectable marker (specifically a kanmycin/neomycin resistance marker) flanked by a pair of recombining sites (specifically LoxP). This plasmid was designed to introduce the recombining site into a genomic locus on a bacterial artificial chromosome (BAC) or a plasmid. A diagram of this plasmid, and a restriction map of this plasmid is shown in the laboratory notes, see page 1. The selection marker is called PL400.

We also constructed PL428 and PL430 which were additional plasmids for introducing recombining sites (LoxP sites) into the 5' and 3' sides of a genomic fragment of the Ctip2 locus. This is documented in the attached photocopy of Dr. Liu's laboratory notes, labeled page 2. DNA fragments of PL428 and PL430 were restriction digested or amplified by polymerase chain reaction. These fragments, containing the selectable marker (Kan-Neo) flanked by two recombining sites (LoxP) and having homology arms, were electroporated into E. Coli cells containing a de-repressible promoter (pL) operably linked to a nucleic acid encoding Beta and Exo. The production of kanamycin resistant cells is documented at the bottom of page 2 ("Kan^R"). A recombinase (Cre) is used to excise the nucleic acid encoding the selectable marker to leave a single first recombining site in the gene, as indicated on the right side of page 3 of the laboratory notes.

To clone a mouse genomic fragment from a BAC using recombineering, in order to make the conditional targeting vector, a retrieval vector (PL433) was constructed. PL433

includes two short DNA fragments from the end of the genomic DNA fragments. There is a MC1TK (thymidine kinase, a second selectable marker) in the backbone of this plasmid, negative selection could be used in embryonic stem cells with this conditional targeting vector. The production of PL433 is documented on page 4 of the laboratory notes.

The PL433 plasmid was electroported into E. coli cells wherein the de-reprssible promoter was de-repressed. Two colonies were examined by digesting the DNA with restriction enzymes. The restriction pattern documented that the selectable marker (TK) was inserted flanked by a second pair of recombining sites (LoxP). This produced plasmid PL435, shown on page 5 of the laboratory notes, which contained the genomic fragment (Ctip2) for making the targeting vector.

The DNA insert (2.8 kb in length) from PL430, which contained the selection marker (Kan-Neo) flanked by two recombining sites (loxP) was co-electroported into bacterial (E. Coli) cells including a derepressible promoter (pL) operably linked to Gam and Exo. The cells were heat induced to insert the first recombining site into the Ctip2 locus. The correctly targeted plasmid was re-transformed into bacterial cells (E. coli). The loxP-flanked Kan marker was excised in the E. coli to leave a single loxP site in the genomic DNA. (see page 6 of the laboratory notes, top panel). This new plasmid was co-electroporated with the DNA fragment from PL436 containing the Neo-Kan selection maker also flanked by a second pair of LoxP sites. This resulted in the production of plasmid PL437. PL437 is the conditional knock-out vector that will allow deletion of the last exon of Ctip2 (see page 6 of the laboratory notes, bottom panel). The configuration of PL437 as a conditional targeting vector was confirmed using restriction digestion, as shown on page 7 of the laboratory notes.

A vector for conditional knock-out of the Evi9 locus was generated. This conditional targeting vector was designed to delete exon 4 of the Evi9 gene. The construction of this vector is shown on page 8 of the laboratory notes.

PL438 was a plasmid that contained a first pair of recombining sites (two LoxP sites, also called "floxed") flanking a selection marker (Neo-Kan), and flanked by two PCR amplified genomic DNA fragments. These genomic fragments could be used as homology arms in recombineering. The insert from this plasmid placed the floxed selection marker (Kan) into the 5' side of exon 4 (within exon 3) of the Evi9 gene. This plasmid could be used to introduce the first recombining sites into a BAC.

PL440 was a plasmid also contained a pair of recombining sites (LoxP or "floxed") flanking a selection marker (Neo-Kan) and flanked by a two polymerase chain reaction (PCR) amplified genomic DNA fragments. PL440 was of uses for recombineering. The insert from PL440 was used to place a floxed selection marker (Kan) into the 3' region of exon 4 (in intron 4) of the Evi9 gene. This plasmid could be used to introducing the second pair of recombining sites into a BAC.

PL441 was then constructed. This is a retrieval vector for retrieving the Evi9 genomic DNA fragment from an Evi9 BAC (see the bottom of page 8 of the laboratory notes). Linearized PL441 was electroported into an Evi9 BAC (called "C3," see page 9 of the laboratory notes). The retrieved plasmid was called PL442. PL442 was co-electroporated with the insert from PL438 to place a floxed Neo-Kan selectable marker into intron 3 of Evi9 (see page 9 of the laboratory notes).

The targeted plasmid was transformed into E. coli expressing a recombinase ("Cre") to excise the selectable marker. This left a single LoxP site in intron 3 of Evi9. The production of this allele is shown in the top panel on page 10 of the laboratory notes.

The excised plasmid was then co-electroporated with the insert from PL440 to place a second floxed selectable marker (Neo-Kan) into intron 4 of Evi9. Thus, the plasmid PL443 was produced, which is a conditional targeting vector that could be used to delete exon 4 (located between intron 3 and intron 4) of Evi9. The production of PL443 is shown in the bottom panels on page 10 of the laboratory notes. We were aware that an Frt site could be used as a recombining site in the place of a loxP site, and that Flp could be used as the recombinase. A strain of *E. Coli*, EL250 was created that expresses Flp.

4. These results demonstrated: (1) homologous recombination could be used to insert a nucleic acid encoding a selectable marker (Neo-Kan) flanked by a pair of first recombining sites (LoxP) into a first site (one intron) in a gene (Evi9 or Ctip2) in vector including bacterial artificial chromosome (Evi9 or Ctip2), (2) homologous recombination could be used to insert a nucleic acid encoding a selectable marker (Neo-Kan) flanked by a pair of second recombining sites (LoxP) and a first recombining site into a second site (a second intron) in the gene (Evi9); (3) the nucleic acid encoding the selectable marker could be excised with a first recombinase specific (Cre) specific for the recombining sites, leaving a single first

recombining site in the gene (Evi9 or Ctip2), and (4) the nucleic acid encoding a selectable marker (Kan-Neo) could be excised with a recombinase (Cre) specific for the second recombining sites. Two recombining sites remained in the gene following excision of the nucleic acid encoding the selectable marker, thus generating a vector for conditional knockout of the gene (Evi9 or Ctip2). *E. coli* strains were created that expressed Flp, so that Frt recombining used. The homologous recombination was performed in bacterial cells including a de-repressible promoter (pL) operably linked to a nucleic encoding Beta and Exo.

5. All statements made herein and of our own knowledge are true and all statements made on information are believed to be true; and further, these statements were made with the knowledge that willful false statements and like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statements made may jeopardize the validity of the application or any patent issuing thereon.

Date _____ _____
Neal G. Copeland

Date 7/26/2006 Daiguan Yu
Daiguan Yu

Date _____ _____
Hilary M. Ellis

Date _____ _____
Donald L. Court

Date _____ _____
E-Chiang Lee

Date _____ _____
Nancy A. Jenkins

Date _____ _____
Pentao Liu

SAS:sas 08/17/06 555051.doc E-177-2000/2-US-02
PATENT

Attorney Reference Number 4239-66898-01
Application Number 10/692,553

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Court et al.
Application No. 10/692,553
Filed: October 23, 2003
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Examiner: Jennifer Ann Dunston
Art Unit: 1636
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Attorney or Agent for Applicant(s)

Date Mailed July 13, 2006
August 21

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

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1. We are the inventors of the above-identified application, which is a continuation of U.S. Patent Application No. 10/366,044, filed February 12, 2003, which is a continuation-in-part of PCT Application No. PCT US01/25507, filed August 14, 2001, which claims the benefit of U.S. Provisional Application No. 60/225, 164, filed August 14, 2000 and claims the benefit of U.S. Provisional Application No. 60/271,632, filed February 21, 2001.

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3. We conceived of, and reduced to practice, a method for generating a vector for conditional knockout of a gene in a cell including a de-repressible promoter operably linked to a

nucleic acid encoding Beta and Exo, as claimed in claims 1, and 2-13, prior to February 13, 2002, in the United States.

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includes two short DNA fragments from the end of the genomic DNA fragments. There is a MC1TK (thymidine kinase, a second selectable marker) in the backbone of this plasmid, negative selection could be used in embryonic stem cells with this conditional targeting vector. The production of PL433 is documented on page 4 of the laboratory notes.

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The targeted plasmid was transformed into E. coli expressing a recombinase ("Cre") to excise the selectable marker. This left a single LoxP site in intron 3 of Evi9. The production of this allele is shown in the top panel on page 10 of the laboratory notes.

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4. These results demonstrated: (1) homologous recombination could be used to insert a nucleic acid encoding a selectable marker (Neo-Kan) flanked by a pair of first recombining sites (LoxP) into a first site (one intron) in a gene (Evi9 or Ctip2) in vector including bacterial artificial chromosome (Evi9 or Ctip2), (2) homologous recombination could be used to insert a nucleic acid encoding a selectable marker (Neo-Kan) flanked by a pair of second recombining sites (LoxP) and a first recombining site into a second site (a second intron) in the gene (Evi9); (3) the nucleic acid encoding the selectable marker could be excised with a first recombinase specific (Cre) specific for the recombining sites, leaving a single first

recombining site in the gene (Evi9 or Ctip2), and (4) the nucleic acid encoding a selectable marker (Kan-Neo) could be excised with a recombinase (Cre) specific for the second recombining sites. Two recombining sites remained in the gene following excision of the nucleic acid encoding the selectable marker, thus generating a vector for conditional knockout of the gene (Evi9 or Ctip2). *E. coli* strains were created that expressed Flp, so that Frt recombining used. The homologous recombination was performed in bacterial cells including a de-repressible promoter (pL) operably linked to a nucleic encoding Beta and Exo.

5. All statements made herein and of our own knowledge are true and all statements made on information are believed to be true; and further, these statements were made with the knowledge that willful false statements and like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statements made may jeopardize the validity of the application or any patent issuing thereon.

Date _____ Neal G. Copeland

Date _____ Daiguan Yu

Date _____ Hilary M. Ellis

Date _____ Donald L. Court

Date _____ E-Chiang Lee

Date _____ Nancy A. Jenkins

Date August 16, 2006 Pentao Liu

recombining site in the gene (Evi9 or Ctip2), and (4) the nucleic acid encoding a selectable marker (Kan-Neo) could be excised with a recombinase (Cre) specific for the second recombining sites. Two recombining sites remained in the gene following excision of the nucleic acid encoding the selectable marker, thus generating a vector for conditional knockout of the gene (Evi9 or Ctip2). *E. coli* strains were created that expressed Flp, so that Frt recombining used. The homologous recombination was performed in bacterial cells including a de-repressible promoter (pL) operably linked to a nucleic encoding Beta and Exo.

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Date _____ Hilary M. Ellis

Date 8/18/2006 Donald L. Court

Date _____ E-Chiang Lee

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Date _____ Pentao Liu

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Date _____ _____
Neal G. Copeland

Date _____ _____
Daiguan Yu

Date _____ _____
Hilary M. Ellis

Date _____ _____
Donald L. Court

Date 8/18/2006 _____
E-Chiang Lee

Date _____ _____
Nancy A. Jenkins

Date _____ _____
Pentao Liu

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Court et al.
Application No. 10/692,553
Filed: October 23, 2003
Confirmation No. 1179
For: ENHANCED HOMOLOGOUS RECOMBINATION MEDIATED BY LAMBDA RECOMBINATION PROTEINS
Examiner: Jennifer Ann Dunston
Art Unit: 1636
Attorney Reference No. 4239-66898-01

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Attorney or Agent for Applicant(s)

Date Mailed ~~July 19, 2006~~ August 22, 2006

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DECLARATION UNDER 37 C.F.R. § 1.131

We, Neal Copeland, Daiguan Yu, Hilary M. Ellis, Donald E. Court, E-Chiang Lee, Nancy A. Jenkins, and Pentao Liu, declare as follows:

1. We are the inventors of the above-identified application, which is a continuation of U.S. Patent Application No. 10/366,044, filed February 12, 2003, which is a continuation-in-part of PCT Application No. PCT US01/25507, filed August 14, 2001, which claims the benefit of U.S. Provisional Application No. 60/225, 164, filed August 14, 2000 and claims the benefit of U.S. Provisional Application No. 60/271,632, filed February 21, 2001.

2. It is our understanding that the claims 1, 3, 4 and 13 are rejected as allegedly being anticipated by Cassanova et al., Genesis 32(2): 158-160, published online February 13, 2002.

3. We conceived of, and reduced to practice, a method for generating a vector for conditional knockout of a gene in a cell including a de-repressible promoter operably linked to a

nucleic acid encoding Beta and Exo, as claimed in claims 1, and 2-13, prior to February 13, 2002, in the United States.

3. The methods of claims 1, 3, 4 and 13 were conceived of prior to February 13, 2003. Selection cassettes for use in the claimed methods were made and improved prior to February 13, 2002; some of the experimental work conducted prior to February 13, 2002 is described below. Photocopies of Dr. Liu's laboratory notebook pages, labeled pages 1-10 are submitted herewith. The photocopied pages are referred to below as "the laboratory notes." Dates on these pages have been redacted. Prior to February 13, 2002, we performed the following experiments in the United States, which are documented on the laboratory notebook pages:

We constructed a plasmid that including a selectable marker (specifically a kanmycin/neomycin resistance marker) flanked by a pair of recombining sites (specifically LoxP). This plasmid was designed to introduce the recombining site into a genomic locus on a bacterial artificial chromosome (BAC) or a plasmid. A diagram of this plasmid, and a restriction map of this plasmid is shown in the laboratory notes, see page 1. The selection marker is called PL400.

We also constructed PL428 and PL430 which were additional plasmids for introducing recombining sites (LoxP sites) into the 5' and 3' sides of a genomic fragment of the Ctip2 locus. This is documented in the attached photocopy of Dr. Liu's laboratory notes, labeled page 2. DNA fragments of PL428 and PL430 were restriction digested or amplified by polymerase chain reaction. These fragments, containing the selectable marker (Kan-Neo) flanked by two recombining sites (LoxP) and having homology arms, were electroporated into E. Coli cells containing a de-repressible promoter (pL) operably linked to a nucleic acid encoding Beta and Exo. The production of kanamycin resistant cells is documented at the bottom of page 2 ("Kan^R"). A recombinase (Cre) is used to excise the nucleic acid encoding the selectable marker to leave a single first recombining site in the gene, as indicated on the right side of page 3 of the laboratory notes.

To clone a mouse genomic fragment from a BAC using recombineering, in order to make the conditional targeting vector, a retrieval vector (PL433) was constructed. PL433

includes two short DNA fragments from the end of the genomic DNA fragments. There is a MC1TK (thymidine kinase, a second selectable marker) in the backbone of this plasmid, negative selection could be used in embryonic stem cells with this conditional targeting vector. The production of PL433 is documented on page 4 of the laboratory notes.

The PL433 plasmid was electroported into E. coli cells wherein the de-reprssible promoter was de-repressed. Two colonies were examined by digesting the DNA with restriction enzymes. The restriction pattern documented that the selectable marker (TK) was inserted flanked by a second pair of recombining sites (LoxP). This produced plasmid PL435, shown on page 5 of the laboratory notes, which contained the genomic fragment (Ctip2) for making the targeting vector.

The DNA insert (2.8 kb in length) from PL430, which contained the selection marker (Kan-Neo) flanked by two recombining sites (loxP) was co-electroported into bacterial (E. Coli) cells including a derepressible promoter (pL) operably linked to Gam and Exo. The cells were heat induced to insert the first recombining site into the Ctip2 locus. The correctly targeted plasmid was re-transformed into bacterial cells (E. coli). The loxP-flanked Kan marker was excised in the E. coli to leave a single loxP site in the genomic DNA. (see page 6 of the laboratory notes, top panel). This new plasmid was co-electroporated with the DNA fragment from PL436 containing the Neo-Kan selection maker also flanked by a second pair of LoxP sites. This resulted in the production of plasmid PL437. PL437 is the conditional knock-out vector that will allow deletion of the last exon of Ctip2 (see page 6 of the laboratory notes, bottom panel). The configuration of PL437 as a conditional targeting vector was confirmed using restriction digestion, as shown on page 7 of the laboratory notes.

A vector for conditional knock-out of the Evi9 locus was generated. This conditional targeting vector was designed to delete exon 4 of the Evi9 gene. The construction of this vector is shown on page 8 of the laboratory notes.

PL438 was a plasmid that contained a first pair of recombining sites (two LoxP sites, also called "floxed") flanking a selection marker (Neo-Kan), and flanked by two PCR amplified genomic DNA fragments. These genomic fragments could be used as homology arms in recombineering. The insert from this plasmid placed the floxed selection marker (Kan) into the 5' side of exon 4 (within exon 3) of the Evi9 gene. This plasmid could be used to introduce the first recombining sites into a BAC.

PL440 was a plasmid also contained a pair of recombining sites (LoxP or "floxed") flanking a selection marker (Neo-Kan) and flanked by a two polymerase chain reaction (PCR) amplified genomic DNA fragments. PL440 was of uses for recombineering. The insert from PL440 was used to place a floxed selection marker (Kan) into the 3' region of exon 4 (in intron 4) of the Evi9 gene. This plasmid could be used to introducing the second pair of recombining sites into a BAC.

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Date 8/21/06 — Neal G. Copeland

Date _____ — Daiguan Yu

Date _____ — Hilary M. Ellis

Date _____ — Donald L. Court

Date _____ — E-Chiang Lee

Date 8/21/06 — Nancy A. Jenkins

Date _____ — Pentao Liu

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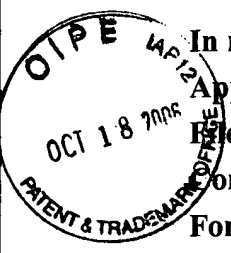

In re application of: Court et al.
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Art Unit: 1636
Attorney Reference No. 4239-66898-01

CERTIFICATE OF MAILING

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Attorney or Agent for Applicant(s)

Date Mailed October 16, 2006

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STATEMENT BY SUSAN ALPERT SIEGEL, PH.D.

Having personal knowledge of the facts set forth below, I declare as follows:

1. I am employed by Klarquist Sparkman, LLP, which represents The Government of the United States of America as represented by the Secretary, Department of Health and Human Services, National Institutes of Health in the above-referenced patent application.

2. Hilary M. Ellis is an inventor of the above-referenced application. At the time the above-referenced application was filed, Hilary M. Ellis resided in San Ramon, CA. It was the undersigned's understanding that Hilary M. Ellis was not employed (outside the home) at that time.

3. A Declaration Under 37 C.F.R. § 131 (hereinafter "the Declaration"), for signature by all of the inventors, was prepared for the response to the Office action dated February 22, 2006. A copy of the Declaration was sent by Express Mail to Hilary M. Ellis at 7598 Interlachen Avenue, San Ramon, CA 94583 on July 25, 2006. On July 28, 2006, the Express Mail envelope was return

to Klarquist Sparkman, stamped non-deliverable. A copy of the Express Mail Label is attached as Exhibit 1.

4. The National Institutes of Health was contacted on August 23, 2006 to determine if updated contact information for Hilary M. Ellis was available. We were informed by the National Institutes of Health that no additional contact information was available. A copy of an e-mail from the National Institutes of Health confirming that there is no additional contact information for Dr. Ellis is enclosed (Exhibit 2). Internet searches were performed to try to locate a new address for Dr. Ellis. However, these searches were not successful. A print-out of an exemplary search is enclosed (Exhibit 3).

5. Accordingly, Hilary M. Ellis is not available to sign the Declaration. Applicants petition that the Declaration be accepted without the signature of Hillary M. Ellis.

6. If any additional fees are required for the acceptance of this petition, please charge Deposit Account No. 02-4550.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

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Susan Alpert Siegel, Ph.D.
Registration No. 43,121

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Susan Alpert Siegel

From: Pontzer, Norbert (NIH/OD) [E] [PontzerN@OD.NIH.GOV]
Sent: Wednesday, September 13, 2006 10:53 AM
To: Susan Alpert Siegel
Subject: Hilary Ellis address

Hi Susan,

Per your 8/23/06 letter concerning the unavailability of Hilary Ellis for purposes of a 131 Dec. to support 10/692,553, our royalty people have apparently been sending royalty checks to:

Hiliary Moyed Ellis
7598 Interlachen Avenue
San Ramon, CA 94583
Phone 925-828-5528 (home)

If this is an address that has not worked for you let me know and I will send you a work order to prepare the documents needed to submit the Dec under these circumstances.

Norb

Norbert Pontzer, J.D., Ph.D.
Technology Licensing Specialist
Office of Technology Transfer
National Institutes of Health
6011 Executive Blvd., Suite 325
Rockville, MD 20852
301-435-5502
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